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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,788	11/06/2001	Michael J. Bonnette	2856.04US01	1848

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EXAMINER

ROBERTS, PAUL A

ART UNIT	PAPER NUMBER
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3731

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DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/007,788

Applicant(s)

BONNETTE ET AL.

Examiner

Paul A Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 3,5-7,10-25,32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,8 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/6/01 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION***Election/Restrictions***

1. The applicant's response to the election requirement in 10/27/03 was originally held to be non-responsive by the examiner. The examiner initiated a telephone interview where the applicant corrected the election. The applicant elected group A -figure 5, group B - figure 9, group c - figures 12-14, without traverse. However, the applicant has made a traversal to the election in the amendment of 1/13/04 anyway. The applicant should have clearly stated on the record in response to the election requirement his arguments as to why the examiner's conception of patentably distinct species was flawed. No such argument was made at that time. Arguendo, as originally presented in the application, there is no disclosure to support that the various handheld pump-sealers illustrated in the drawings (figures 1, 5, 6, 7-8, 10, 11, or 19) are the same embodiment. The species appear in the drawings to be quite different from one another and the specification refers to them as dissimilar embodiments. For example, "Figures 5-7 are views of alternate embodiments of the inflation/deflation system". The applicant has argued that there are only two species of invention with regard to handheld device, the device of figures 7-9 and the device of figures 5-6. This argument is irrelevant because there are 7 species of handheld device as explained above and acknowledged in the interview summary. The applicant has elected the species of figure 5, and only claims generic to that species will be examined. The requirement is still deemed proper and is therefore made FINAL.

Status of claims:

Claims 1, 2, 4, 8, and 9 are elected.

Claims 3, 7, 11, 15, 18-25, and 32-33 are withdrawn by the applicant.

Claims 5-6, 10, 12-14, 16, and 17 are withdrawn by the examiner because they do not read on the applicant's elected invention. The reasons why these claims do not read the applicant's elected invention can be found in the Office action of 12/12/03 and are reproduced below:

Reasons why the claims do not read on the elected species:

Regarding claims 3 and 18, the applicant has elected figure 5. The disclosure does not enable one of ordinary skill in the art to build a device having 1st and 2nd aperture because the specification does not mention any apertures in the embodiment of figure 5 nor does figure 5 show 2 apertures. Further, no handheld structure is supported by the specification for figure 5. There is no label in the specification for a handheld device in figure 5. Specifically for claim 3, there does not appear to be a passageway 70 in figure 5. Also, as required by claim 18, there are no conduits shown or disclosed in the specification for figure 5. Claims 20 and 22 do not read on figure 5 because claim 18 does not read on figure 5.

Regarding claims 5 and 6, the depressible roller mechanism is not disclosed for figure 5. Further, figure 5 does not appear to have a first roller, or a second roller. There is no disclosure of a threshold force as it relates to figure 5.

Regarding claim 10, figure 5 does not disclose a removable sealing assembly. The specification does not disclose the sealing assembly can be removed. In fact, the figure shows the sealing assembly to be unitary in construction. Claims 11-14, and 16-17 do not read on the figure because they are dependent on claim 10.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the hand-held apparatus must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. From the disclosure, it appears the handheld apparatus is just a label for the combined structure of elements 60 and 80. Nonetheless, the apparatus needs a label on the drawings and that label needs to be recited in the specification.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Valley et al. (Valley) US 6251093. Valley discloses a gas inflation/evacuation system removably connectable to a proximal portion of a guidewire assembly, comprising: means for evacuating air from the guidewire assembly (col. 16, 5-15); and means for introducing a biocompatible gas (col. 13, 45-50) into the guidewire assembly (897, figure 34) to inflate an occlusive balloon proximate

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a distal end of the guidewire assembly a plurality of times; and means (col. 38, line 12-19) for selectively sealing the proximal portion of the guidewire assembly at one of a plurality of separate locations to form one of a plurality of airtight seals of the guidewire assembly.

4. Regarding claim 2, the system has a pump that adds/removes air. A pump is handheld.
5. Regarding claim 4, the system contains a means for sealing that comprises a crimping mechanism.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valley '093. Valley does not go into detail about how to package the surgical instrument of claim 1. It is common practice to package a surgical device in sterile packaging within a vessel containing biocompatible gas. One would place the device in sterile packaging to prevent possible contamination of the device leading to patient infections. Additionally, one would package the device in a field containing biocompatible gas because using a non-biocompatible gas would likely cause the patient to adversely react to the treatment. At the time of the invention it would have been obvious to one having ordinary skill in the art to package the device with sterile packaging and to package the device in a vessel or field containing biocompatible gas because

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both practices are well-known in the art, and not following those practices would inevitably lead to adverse patient post-surgical reactions.

Response to Arguments

7. Drawings: the applicant has asked the examiner to hold the drawing objection in abeyance. Please see the second paragraph of the drawing objection.

8. Page 11, paragraph 2 of the applicant's response: in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the ability of the Valley device to track a catheter, or the size of the device) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

9. Page 11, paragraph 3 through page 12, paragraph 1: the Valley device can inherently be inflated and deflated a plurality of times. The device is capable of this feature. In response to applicant's argument that the Valley device is not intended to be used in a procedure where the balloon would be inflated and deflated a plurality of times, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

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10. Page 12, paragraph 1, the limitations of claim 1 require the device to have a means capable of evacuating air from a guidewire assembly, and inflating the balloon a plurality of times. Since the balloon of Valley can be inflated and deflated with gas, it can be inherently inflated and deflated a plurality of times. As far as the argument about whether or not Valley discloses the method of inflating and deflating the balloon a plurality of times, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

11. Page 12, paragraph 2, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the purpose of selectively sealing the proximal portion of the guidewire with a crimp) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The crimp of Valley forms an airtight seal on the proximal portion of the guidewire device.

12. Page 12, paragraph 3, the applicant has argued that the Valley doesn't contain a pump. This argument is not persuasive because the scope of the term pump is larger than the applicant apparently realizes. For the purpose of this claim, a pump is a device used to move fluid. A

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syringe is clearly within the scope of a pump and thus the Valley reference anticipates the claim.

The syringe can be used inflate or deflate the balloon on the Valley device.

13. Page 13, paragraph 3, as described above Valley discloses the method of inflating and deflating the balloon with a biocompatible gas. The applicant is arguing the method of packaging the device only in biocompatible gas and sealing the package so the package contains only the gas and the device, is not well known in the art. Air, as in the gas surrounding the Earth, is biocompatible. It is exceedingly well known in the art to package a device in sterile packaging where the surrounding gas in the device is air. Thousands of medical devices are assembled in clean rooms and placed sterile packaging with a small fraction of the air (which biocompatible) in the packaging. Applicant may wish to consult US 6488801, US 6481468, or US 20020156486, if he needs further evidence this process is well known.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

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03/16/04


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